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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/904,201 07/11/2001 Eugene de Juan JR. 56247 (71699) 1217 21874 12/13/2004 **EXAMINER** 7590 **EDWARDS & ANGELL, LLP** DEMILLE, DANTON D P.O. BOX 55874 BOSTON, MA 02205 ART UNIT PAPER NUMBER 3764

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | |
|--|--|-------------------------------------|-----------------------------|--|
| Office Action Summary | | 09/904,201 | JUAN ET AL. | |
| | | Examiner | Art Unit | |
| | | Danton DeMille | 3764 | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | |
| Status | | | | |
| 1)⊠ | Responsive to communication(s) filed on 14 Se | eptember 2004. | | |
| 2a)⊠ | This action is FINAL . 2b) ☐ This | action is non-final. | | |
| 3)□ | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | |
| Disposition of Claims | | | | |
| 5)⊠ 6)⊠ 7)□ | 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 1-9 and 15-20 is/are allowed. 6) Claim(s) 10-14 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | |
| Application Papers | | | | |
| 9) The specification is objected to by the Examiner. | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | |
| Attachment(c) | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | |
| 2) Notic | e of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | ate | |
| • | mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) or No(s)/Mail Date | 5) Notice of Informal P 6) Other: | atent Application (PTO-152) | |

Application/Control Number: 09/904,201

Art Unit: 3764

DETAILED ACTION

Claim Rejections - 35 USC § 103

- 1. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. in view of Sahatjian and further in view of Krasner.
- 2. Regarding claim 10, Yamada already teaches mounting the deflated lens on the moveable member 28, moving the moveable member from a first position to a second position deploying the lens, forming the intraocular lens by injecting a medium into the lens and removing the moveable member from the eye.
- 3. Sahatjian teaches the conventional outer member 30 that contains and protects the inner inflatable moveable member. It would have been obvious to one of ordinary skill in the art to modify Yamada to use a separate outer tube around the inner inflatable moveable member as taught by Sahatjian to protect the human tissue and protect and guide the inflatable member to its destination.
- 4. Yamada teaches that the tube 14 is filled with and closed by the gel filler 16. "When a catheter, for example, is inserted through the tube 14 in order to inject the fluid into the balloon member 12, the injected fluid is not allowed to pass through the tube 14 due to the presence of the gel filler 16 filling the space between the catheter and the tube 14. When the catheter is then pulled out of the tube 14, the bore of the tube 14 is spontaneously closed due to the auto—sealing property of the gel filler 16." The gel filler 16 allows insertion of a catheter and removal of the catheter for the purpose of filling the balloon member 12. The gel filler 16 would allow the function of re-inserting the catheter into the balloon to adjust the amount of medium in the lens. Even after initially injecting the lens with the fluid if upon removal of the injection device

Application/Control Number: 09/904,201

Art Unit: 3764

it is determined that either more fluid or less fluid is needed on can always reinsert the injection device to adjust the amount of fluid within the balloon. Such is well within the realm of the artisan of ordinary skill. Krasner exemplifies this in column 3, lines 15-28, by providing a self-sealing portion of the balloon for inserting an injection device in the lens for adjusting the amount of fluid within the lens. It would have been obvious to one of ordinary skill in the art to further modify Yamada to re-insert an injection device in the lens to adjust the amount of fluid in the lens as taught by Krasner to modify the optical characteristics as needed.

Response to Arguments

- 5. Applicant's arguments filed 14 September 2004 have been fully considered but they are not persuasive.
- 6. Applicant argues that Yamada fails to teach that at a later date one can re-insert an injection device into the intraocular lens and adjust the amount of optical medium in the intraocular lens. The additional step is not new. Krasner teaches such a convention as noted above. There appears to be no unobviousness to provide this same functionality to Yamada. Both teach an intraocular lens that has a self-sealing portion for the purpose of allowing injection devices to be inserted into the lens for inflating the lens and removing the injection device through the self-sealing portion.
- Applicant states that Sahatjian and Krasner either alone or in combination do not remedy such deficiencies of Yamada. It is not clear how applicant can disregard the teaching of Krasner. As set forth in the previous office action Krasner does teach the convention of reinserting an injection device into the lens for controlling the amount of fluid within the lens.

Conclusion

- 8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- 9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974. The examiner can normally be reached on M-Th from 8:30 to 6:00. The examiner can also be reached on alternate Fridays
- If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
- 12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 3764

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Danton DeMille Primary Examiner Art Unit 3764